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Withdrawal of application to change the marketing authorisation for Tecentriq (atezolizumab)

Roche Registration GmbH withdrew its application for the use of Tecentriq to treat early or locally advanced triple-negative breast cancer.

The company withdrew the application on 23 June 2021.

What is Tecentriq and what is it used for?

Tecentriq is a cancer medicine for treating:

- urothelial cancer (cancer of the bladder and urinary system)
- lung cancer
- hepatocellular carcinoma, a cancer that starts in the liver.
- a type of breast cancer known as triple-negative breast cancer.

Tecentriq has been authorised in the EU since September 2017. It contains the active substance atezolizumab and is given as an infusion (drip into a vein).

Further information on Tecentriq's uses can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/tecentriq

What change had the company applied for?

The company applied to extend the use of Tecentriq in treating triple-negative breast cancer. Currently Tecentriq is used with nab-paclitaxel when the cancer cannot be removed by surgery. The company also wanted Tecentriq to be used before surgery in patients with early or locally advanced triple-negative breast cancer in combination with nab-paclitaxel and anthracycline-based chemotherapy.

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How does Tecentriq work?

The active substance in Tecentriq, atezolizumab, is a monoclonal antibody, a type of protein designed to recognise and attach to a protein called PD-L1 (programmed death-ligand 1), which is present on many cancer cells.

PD-L1 acts to switch off immune cells that would otherwise attack the cancer cells. By attaching to PD-L1 and reducing its effects, Tecentriq increases the ability of the immune system to attack the cancer cells and thereby slow down progression of the disease.

What did the company present to support its application?

The company presented data from an ongoing main study of 333 patients who received either Tecentriq or placebo (a dummy treatment) in combination with nab-paclitaxel and anthracycline-based chemotherapy, before going on to have surgery. The main measure of effectiveness was how many patients no longer had tumours in their breasts or lymph nodes after surgery. Patients were followed-up afterwards to assess longer-term benefits and to see if their cancer came back

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's responses to the questions, there were still some unresolved issues.

What did the Agency recommend at that time?

Based on the review of the information and the company's response to the Agency's questions, at the time of the withdrawal, the Agency had some concerns and its provisional opinion was that the use of Tecentriq could not be extended.

The Agency noted that the effect of Tecentriq in the main study was not sufficient to establish that the medicine worked well enough when given with other medicines before surgery for triple-negative breast cancer. Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Tecentriq did not outweigh its risks in the treatment of early or locally advanced triple-negative breast cancer before surgery in combination with nab-paclitaxel and anthracycline-based chemotherapy.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated it withdrew the application because data from the main study did not allow the CHMP to conclude that the benefit-risk balance was positive.

Does this withdrawal affect patients in clinical trials?

There are no consequences for patients who are receiving Tecentriq in clinical trials. If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.

What is happening with Tecentriq in its other uses?

There are no consequences on the use of Tecentriq in its existing uses.